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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/368,776	01/03/95	CIOSSEK	T

022249
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HM12/1213

EXAMINER	
UNGAR, S	
ART UNIT	**PAPER NUMBER**
1642	28

DATE MAILED: 12/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applica(nt)s)
08/368,776	Ciossek et al
Examiner	**Group Art Unit**
Ungar	1642

☒ Responsive to communication(s) filed on *Apr 6, 1998*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-4, 16-19, 21, 22, and 24-26* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-4, 16-19, 21, 22, and 24-26* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. A reference relevant to the examination of this application has become available, therefore, *Ex parte* prosecution is resumed.

2. Upon review and reconsideration, the Finality of the previous Office Action is withdrawn.

3. The Amendment filed August 12, 1997 (Paper No. 23) is acknowledged and has been entered. Claim 26 has been amended. Claims 1-4, 16-19, 21, 22 and 24-26 are pending and currently under prosecution.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Objection

Specification

4. The specification is objected to because of he following informalities:

(A) The Brief Description of the Drawings andd the Drawings are objected to because Figures 1-3 contain sequences which are not identified by unique sequence identification numbers.

(B) Page 94 recites probes which correspond to specific nucleotides of MDK1 and MDK1.T1. However, there are no unique sequence number identifier recited that would allow the skilled artisan to identify these probes since neither the Brief Description of the Drawings nor the Drawings disclose said identifiers. Examiner has made an effort to identify these informalities but applicant must carefully review the specification to identify and indicate where such informalities may be found. Appropriate correction is required.

It is noted that Applicant was informed by Voice Mail on November 18, 1996 (see Paper No. 15) that submitted SEQ ID Nos 3, 5, 11 and 12 do not match sequence information in the specification. Fig 2A shows MDK1.T1 with 988 nucleotides, SEQ ID NO:3 has 1830 nucleotides, Fig 2A shows MDK1.T2 with 321 nucleotides, SEQ ID NO:5 has 1878 nucleotides. Fig 2B shows MDK1.delta 1 with 87 amino acids, SEQ ID NO:11 has 2979 amino acids. Fig 2B shows MDK1.delta 2 with 88 amino acids, SEQ ID NO:12 has 2982 amino acids. Applicant has not clarified the differences between the submitted sequences and those shown in the figures as originally submitted.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

5. Claims 1-4, 16-17, 21, 22 and 24-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for a nucleic acid encoding a MDK1 polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2, said sequence and a vector and said sequence and a translational termination region functional in a cell, does not reasonably provide enablement for a nucleic acid that hybridizes under stringent conditions to said nucleic acid, or a nucleic acid that hybridizes under stringent conditions to said nucleic acid and a vector or a nucleic acid that hybridizes under stringent conditions to said nucleic acid and a translational termination region functional in a cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to a nucleic acid that hybridizes under stringent conditions to a nucleic acid that encodes a polypeptide encoding a MDK1 polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2. This includes any nucleic acid that binds under stringent conditions which are not defined by the claim. The specification teaches that the nucleic acids of the invention are to be used to express MKD1 polypeptides, as hybridization probes for detecting MDK1 RNA (p. 10), production of transgenic animals, (p. 22) and used in methods for diagnosis and treatment of disorders associated with abnormalities of a signal transduction pathway (p. 5). Further, the specification states that various low and high stringency hybridization conditions may be used depending upon the specificity and selectivity desires and that under stringent hybridization conditions only highly complementary nucleic acid sequences hybridize and that preferably such conditions prevent hybridization of nucleic acids having 1 or 2 mismatches out of 20 contiguous nucleotides (p. 10, lines 1-8). It is noted that highly complementary nucleic acid sequences are not defined. One cannot extrapolate the teaching of the specification to the scope of the claims because the specification does not teach how to use the nucleic acids that hybridize to the claimed nucleic acid encoding SEQ ID NO:2 under stringent conditions. When given the broadest reasonable interpretation, the claims are clearly intended to encompass a variety of species including full-length cDNAs, genes and protein coding regions. Clearly, it would be expected that a substantial number of the hybridizing nucleic acids encompassed by the claims **would not** share either structural or functional properties with polynucleotides that encode SEQ ID NO:2. It is not clear how these species could be used as

hybridization probes for detecting MDK1, for the production of transgenic animals, or used in methods for diagnosis and treatment of disorders associated with abnormalities of a signal transduction pathway.The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art on how to use the broadly claimed species. For the above reasons, undue experimentation would be required to practice the claimed invention.

6. Claims 1-4, 16-17, 21, 22 and 24-26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 16-17, 21, 22 and 24-26 are indefinite because claims 1-4 recite the phrase "that hybridizes under stringent conditions". Stringent conditions are not defined by the claim. Although the specification states that various low and high stringency hybridization conditions may be used depending upon the specificity and selectivity desires and that under stringent hybridization conditions only highly complementary nucleic acid sequences hybridize and that preferably such conditions prevent hybridization of nucleic acids having 1 or 2 mismatches out of 20 contiguous nucleotides (p. 10, lines 1-8), there is no definition of what is meant by highly complementary nucleic acid sequences, no specific limitations have been set for stringent conditions and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and would not be able to determine the metes and bounds of the claims.

Claims 1-4, 16-17, 21, 22 and 24-26 are indefinite because claims 1-4 recite the phrase "a nucleotide encoding MDK1". The claims are confusing because it is not clear how a single nucleotide could encode MDKA protein since it is well known in the art that three nucleotides are required to encode even a single amino acid residue.

Claims 21, 22, 24 and 25 are indefinite because they recite ranges of amino acid sequences of Figure 1 but do not cite specific SEQ ID Nos. A review of Figure 1 and the Brief Description of Figure 1 reveals that neither Figure 1 nor the Brief Description of Figure 1 discloses SEQ ID Nos for the disclosed sequences.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

8. Claims 1-4 are rejected under 35 USC § 102(b) as being anticipated by WO9300425.

It is noted that the nucleic acid of SEQ ID NO:1 encodes SEQ ID NO:2.

It is noted that although methods of using probes are described on pages 10 and 33-34 of the specification, a probe is not defined by the specification. The

preamble recitation of "a probe for the detection of" is merely suggestive of an intended use and is not given weight for purposes of comparing the claims with the prior art. The claims read on the active ingredient *per se*, which is a nucleic acid molecule that hybridizes under stringent conditions to the polynucleotide encoding SEQ ID NO:2 or a nucleic acid molecule that hybridizes under stringent conditions to a polynucleotide that hybridizes under stringent conditions to the nucleic acid molecule that encodes SEQ ID NO:2.

The claims are drawn to a nucleic acid that hybridizes under stringent conditions to the nucleic acid molecule that encodes SEQ ID NO:2 (claim 1), a probe that hybridizes under stringent conditions to the nucleic acid molecule that encodes SEQ ID NO:2 or a nucleic acid molecule that hybridizes to said nucleic acid molecule (claim 2), a nucleic acid that hybridizes under stringent conditions to the nucleic acid molecule that encodes SEQ ID NO:2 and a vector or promoter effective to initiate transcription in a cell (claim 3), a nucleic acid that hybridizes under stringent conditions to an RNA sequence encoding SEQ ID NO:2 and a translational terminal region functional in a cell (claim 4).

WO9300425 teaches a nucleic acid with identity to 1860 residues of SEQ ID NO:1 over a range of 3004 nucleotides with numerous stretches of identical consecutive residues ranging from two to seventeen consecutive amino acids (see above) which would be expected to hybridize under stringent conditions to a nucleotide that hybridizes under stringent conditions to the nucleotide encoding SEQ ID NO:2 (that is SEQ ID NO:1) and teaches sequences complementary to said sequence (Claim 6) which would be expected to hybridize to SEQ ID NO:1 under

stringent conditions (claims 1 and 2) and teaches nucleic acid vectors containing said nucleic acid sequences capable of expression in both eukaryote and procaryote host cells and teaches that the general techniques of recombinant DNA technology including isolation of expressed proteins are well known in the art (page 10). It would be an inherent property of the expression vector to include a translational termination region functional in a cell. (claims 3 and 4).

9. Claims 16 and 18 are rejected under 35 USC § 102(b) as being anticipated by WO9300425.

The claim 16 is drawn to a nucleic acid comprising a nucleic acid sequence of SEQ ID NO:1. Claim 18 is drawn to a nucleic acid comprising a nucleic acid sequence of SEQ ID NO:3 or 4.

WO9300425 teaches a nucleic acid sequence that not only comprises a nucleic acid sequence of SEQ ID NO:1, see claim 6 and Figure 1, but comprises more than 150 nucleic sequences of SEQ ID NO:1 ranging from two to seventeen consecutive nucleotides (see also Sequence Search us08-3680776A-1.rng Result 8).

WO9300425 teaches a nucleic acid sequence that not only comprises a nucleic acid sequence of SEQ ID NO:3, see claim 6 and Figure 1, but comprises more than 150 nucleic sequences of SEQ ID NO:3 ranging from two to five consecutive nucleotides (see also Sequence Search us08-3680776A-3.rng Result 4).

10. Claim 22 is rejected under 35 U.S.C. § 102(e) as being anticipated by US Patent No. 5,981,246.

It is assumed for examination purposes that Figure 1 discloses the amino acid sequence of SEQ ID NO:2

The claim is drawn to a nucleic acid comprising a nucleic acid sequence of claim 1 encoding the MDK1 polypeptide transmembrane domain as shown by amino acids 555-579 of Figure 1. It is assumed for examination purposes that Figure 1 discloses the amino acid sequence of SEQ ID NO:2.

US Patent No. 5,981,246 discloses a polypeptide which comprises amino acids 555-579 of SEQ ID NO:2 (see amino acids 555-579 of SEQ ID NO:17, Figure 4) and teaches a nucleic acid which encodes these amino acids. The nucleic acid comprises a nucleic acid sequence encoding the MDK1 polypeptide transmembrane domain as shown by amino acids 555-579 of Figure 1. All of the limitations of the claims are met.

7. All other objections and rejections recited in Paper No. 21 are withdrawn

8. No claims allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.

Susan Ungar
Primary Patent Examiner
November 24, 1999

PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER